Exhibit 191

REDACTED

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

IN RE: VALSARTAN, LOSARTAN, AND IRBESARTAN PRODUCTS LIABILITY LITIGATION	**No. 1:19-md-2875-RBK**

EXPERT DECLARATION OF PROFESSOR PUNAM A. KELLER, Ph.D.

January 12, 2022

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I. Introduction

A. Assignment

1. I have been asked by counsel for Defendants to review health care decision making and how valuation of valsartan containing drugs ("VCDs")[1] should be viewed in light of the voluntary recall of certain VCDs in 2018 and 2019. As part of this assignment, I have been tasked with evaluating certain assertions from Plaintiffs' expert Dr. Rena Conti, particularly her claim that the VCDs at issue in this case were "worthless" to consumers as a result of the VCD recalls.

B. Qualifications

2. I am the Charles Henry Jones Third Century Professor of Management, a chaired professor in the marketing area, and Senior Associate Dean at the Tuck School of Business at Dartmouth College in Hanover, New Hampshire. I hold a B.A. in Economics & Statistics from Bombay University, an MBA in Marketing from the Bajaj Institute of Management at Bombay University, and a Ph.D. in Marketing from Northwestern University.

3. Over the course of my career, I have taught courses at the MBA, Masters in Health Care Delivery Science (MHCDS), Executive MBA, and Ph.D. levels in subjects including Marketing Management, Marketing Strategy, Marketing Research, Social Marketing, Strategic Health Marketing, and Consumer Behavior. My research develops theory on

[1] There are four types of valsartan-containing drugs: (1) valsartan; (2) valsartan and hydrochlorothiazide; (3) valsartan and amlodipine; and (4) valsartan, hydrochlorothiazide, and amlodipine. *In Re: Valsartan, Losartan, and Irbesartan Products Liability Litigation,* No. 1:19-md-2875-RBK, Third Amended Consolidated Economic Loss Class Action Complaint, November 1, 2021 ("Complaint"), ¶ 3. Herein, the term VCDs is used to refer to any valsartan or valsartan combination product.

how people process marketing communications, in particular health appeals, and includes the application of social marketing principles and behavioral theory to enhance voluntary consumer and employee health and saving behaviors. In addition, my research evaluates social marketing techniques and their impact on individual and collective well-being. My recent publications aim to promote appropriate medication prescribing through effective behavioral communication nudges to physicians and patients. I have published my research in medical journals (including *BMJ Open, J Med Internet Res, Implementation Science (BioMedCentral)*, and *Health Communications*) on topics related to medication compliance. My research also appears in several top peer-reviewed marketing journals (including the *Journal of Marketing Research*, *Journal of Consumer Research*, and *Journal of Consumer Psychology*) on topics related to marketing in the context of health, in particular social marketing related to health communication and consumer health. I became a Fellow of the Association for Consumer Research in 2018; this award recognizes lifetime significant impact on scholarly work in consumer behavior. I have also served as a reviewer or editor for 12 different academic journals, including current positions on the Review Board of the *Journal of Marketing*, *Journal of Marketing Research*, *Journal of Public Policy and Marketing*, and *Social Marketing Quarterly*.

4. I have also advised several organizations in the health sector regarding health-related communications. I worked with the Centers for Disease Control and Prevention's Division of Cancer Prevention and Control to design an online health communication marketing tool (MessageWorks) to help health researchers and practitioners develop effective health messages. In addition, I have created health messages to increase prescription drug adherence for CVS Health. Similarly, I have created health messages for the Mayo Clinic

to help reduce heart failure readmission rates. I currently serve on the research committee for the Brigham and Women's Hospital's Roybal Center for Therapeutic Optimization Using Behavioral Science. I am on the investigating research team and/or provide research consultant support for several medical-related grants, including grants from the National Institutes for Health, National Institutes for Aging, and National Cancer Institute.

5. A copy of my curriculum vitae summarizing my background and qualifications, including cases in which I have testified as an expert at trial or by deposition in the last four years, is attached as **Appendix A**.

6. I am being compensated at my standard rate of $1,000 per hour. In addition, employees of Analysis Group, working under my direction and supervision, have assisted me in this assignment at standard hourly rates charged by that firm. Neither my compensation nor that of Analysis Group is contingent on the nature of my findings or the outcome of this litigation.

C. Declaration Preparation

7. In preparing this declaration, I have reviewed legal filings, deposition testimony, case materials, academic research, and other publicly available information. My opinions and conclusions are based on my understanding of the issues involved in this matter derived from documents and other materials that I have reviewed, together with my training, education, and experience. My work in this matter is ongoing and I reserve the right to supplement my opinions and conclusions in the event that documents, testimony, expert reports/declarations, or other materials become available. A list of materials that I considered in forming the opinions in my declaration is attached as **Appendix B**.

II. Summary of Opinions

8. The opinions I have reached regarding consumer behavior and perception of value following the recalls of certain VCDs are as follows:

- Consumers employ a variety of decision rules and approaches in the healthcare context, each depending on their individualized circumstances. The "compensatory decision-rule" is commonly used to understand healthcare decision-making, and is an appropriate model to apply to assess the potential change in value to consumers, if any, following the recalls of certain VCDs. In the healthcare context, consumers often apply a compensatory decision-rule whereby they assign different weights to different features. As to prescription drugs, they often place a higher value on one feature to compensate for a lesser value of another feature. Consumers continually make risk trade-offs when weighing the drug's costs and benefits. This is in contrast to the "non-compensatory decision-rule," pursuant to which value assessment is binary, i.e., a "yes" (positive value) or "no" (zero value) on any one dimension, such as price or dosage form. Consumers frequently compare across multiple features simultaneously, assigning different "importance weights" to different features, rather than making a binary assessment of value based on just one feature.

- Health decision making depends on 3 key factors: (1) ***Message*** (e.g., what information consumers receive), (2) ***Individual characteristics*** (e.g., unique medical history and health profiles), and (3) ***Context*** (e.g., physician trust and social norms), as well as the ***Interaction*** of these three factors ("MICI").

- Consumers purchased the at-issue VCDs when they were on the market, prior to the recalls, when the presence of the potential nitrosamine impurities was unknown. If those consumers were to assess the value of those VCDs retrospectively, knowing what is known now about the impurities, consumers utilizing the compensatory decision-rule with the MICI factors would provide a range of value responses. This follows from the fact that each consumer can place different weights on different features as part of their valuation process. To examine consumers' retrospective valuation of at-issue VCDs that they have already consumed and have already derived therapeutic value from, it is important to recognize that consumers would each react distinctively and differently to the knowledge that there may have been impurities in the VCDs that they purchased.

- Specifically, real-world evidence indicates that the at-issue VCDs held value, which varied by consumer. To determine how consumers would retrospectively value those VCDs that they previously purchased is an individualized inquiry. Many of the consumer plaintiffs in this case admit that the at-issue VCDs were effective in treating their hypertension. Some consumers likely would place significant value on the benefits like this that they received from the at-issue VCDs regardless of the potential presence of impurities, while other consumers would assess different levels of perceived or potential negative impact resulting from the impurities. It is likely that a spectrum of consumer valuations would exist in this case given these varied assessments of the benefits of the at-issue VCDs and the risks perceived from the impurities.

9. The opinions I have reached in response to the analysis conducted by Dr. Conti with respect to consumers are as follows:

- Dr. Conti's analysis is overly simplistic and does not account for the realities of the healthcare decision making process. Dr. Conti assumes the value of the at-issue VCDs that consumers purchased when they were on the market has retroactively become zero because some of them were later recalled due to the impurities. In doing so, Dr. Conti's analysis implicitly relies on a uniform non-compensatory decision-rule for calculating damages. Her damages calculation assumes that the entirety of the value generated from the at-issue VCDs over the at-issue period was destroyed by one feature—the potential existence of the impurities—without considering any other features such as therapeutic value. In reality it is likely that many consumers, utilizing a compensatory decision-making process, would still attribute (and in fact did attribute) significant positive value to the at-issue VCDs after becoming aware of the impurities and re-evaluating their consumption of those VCDs.

- Dr. Conti's analysis is not consistent with the goal of attempting to determine potential economic damages, if any, to consumers since it ignores the fact that consumers did receive the at-issue VCDs, and how the change in demand for those VCDs due to the actual or potential impurities (if any) would appear in the demand curve. To understand potential economic damages to consumers, one would need to adjust the demand curve to reflect the fact that consumers might value VCDs containing impurities differently than VCDs without impurities. In conducting this analysis, one would need to examine the impurities' idiosyncratic impact on demand. Specifically, it

is prudent to analyze how the full spectrum of consumers would distinctively react to the impurities, or potential impurities, in the VCDs that they purchased.

III. Background and Overview of Dr. Conti's Declaration

A. Parties Involved

1. Defendants

10. The defendants in this case are divided into the following categories: Active Pharmaceutical Ingredient Manufacturer Defendants; Finished-Dose Manufacturer Defendants; Retail Pharmacy Defendants; Wholesaler Defendants; Repackager and Relabeler Defendants; and True Names/John Doe Defendants.[2] The defendants represent the different levels of the supply chain for the VCDs at issue, including the manufacturers of the active pharmaceutical ingredient, the manufacturers of the finished-dose VCDs, the distributors/wholesalers, and the pharmacies/retailers.[3]

2. Plaintiffs

11. I understand that there are three types of plaintiffs in this case: (1) economic loss; (2) medical monitoring; and (3) personal injury. I further understand that I am providing opinions as to the economic loss plaintiffs. There are two categories of economic loss plaintiffs. The first is the individual consumers who paid for a VCD that was manufactured, distributed, or sold by any Defendant; and the second are the TPPs that paid for a VCD that was manufactured, distributed, or sold by any Defendant.[4] The individual consumer economic loss plaintiffs belong to a variety of proposed sub-classes

[2] Complaint, ¶¶74-163.

[3] Complaint, ¶¶ 74, 80, 81, 87, 93, 107, 142, 143.

[4] Complaint, ¶ 603-604.

listed in Exhibit A to Plaintiffs' Motion for Class Certification of Consumer, Third Party Payor, and Medical Monitoring Claims.[5] I am providing opinions as to the consumer economic loss plaintiffs.

B. Plaintiffs' Allegations

12. Plaintiffs' Third Amended Consolidated Economic Loss Class Action Complaint ("Complaint") purportedly arises from the sale of VCDs that contained nitrosamine impurities and "were designed, manufactured, labeled, marketed, distributed, packaged, and sold by Defendants…in the United States, and/or for ultimate sale in the United States."[6] VCDs are medications used to help treat various heart conditions. Specifically, valsartan is an "orally active nonpeptide tetrazole derivative which causes a reduction in blood pressure, and is used in the treatment of hypertension, heart failure, and postmyocardial infarction."[7]

13. Plaintiffs allege that the nitrosamine impurities in some VCDs rendered the at-issue VCDs worthless and that Plaintiffs suffered economic damages through the purchase of allegedly "worthless" drugs over the class period.[8] Furthermore, Plaintiffs allege that no reasonable consumer would purchase "contaminated" drugs.[9]

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[5] *In Re: Valsartan, Losartan, and Irbesartan Products Liability Litigation,* No. 1:19-md-2875-RBK, Plaintiffs' Motion for Class Certification of Consumer, Third Party Payor, and Medical Monitoring Claims, November 10, 2021, Ex. A.

[6] Complaint, ¶ 2.

[7] Complaint, ¶ 263.

[8] Complaint, ¶¶ 408, 423.

[9] Complaint, ¶ 423.

14. Not all of Defendants' VCDs contained nitrosamine impurities or were recalled.[10] Plaintiffs' consumer class definition, however, includes any individual who purchased a valsartan-containing drug that was manufactured, distributed, or sold by any Defendant, regardless of whether that drug was recalled or actually contained any impurities (the "at-issue VCDs").[11]

C. Overview of Dr. Conti's Declaration

15. Dr. Conti purports to calculate "damages for four different theories of liability against the Manufacturer Defendants and two different theories of liability and one theory of unjust enrichment against the Defendant Retailers."[12] Dr. Conti also purports to develop a methodology for calculating Defendant Wholesalers' unjust enrichment damages.[13] Dr. Conti ultimately claims aggregate damages against the Defendant Manufacturers of [redacted] for the Consumer Class, aggregate damages against the Defendant Retailers of [redacted] for the Consumer Class, and unjust enrichment damages against the Defendant Retailers of [redacted] for the Consumer Class.[14] Dr. Conti does not appear to calculate Wholesalers' damages.

[10] "AurobindoPharma USA, Inc. Initiates a Voluntary Nationwide Consumer Level Recall Expansion of 38 lots of Amlodipine Valsartan Tablets USP and Valsartan Tablets, USP due to the detection of NDEA (N-Nitrosodiethylamine) Impurity." *U.S. Food & Drug Administration ("FDA"),* March 1, 2019, available at https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/aurobindopharma-usa-inc-initiates-voluntary-nationwide-consumer-level-recall-expansion-38-lots, accessed on January 12, 2022 (Aurobindo recall involved only certain lots).

[11] Complaint, ¶¶ 603, 604.

[12] Expert Declaration of Rena Conti, Ph.D., *In Re: Valsartan, Losartan, and Irbesartan Products Liability Litigation*, No. 1:19-md-2875-RBK, November 10, 2021 ("Conti Declaration"), ¶ 58.

[13] Conti Declaration, ¶ 80.

[14] Conti Declaration, ¶ 9.

16. Dr. Conti provides many different formulas for calculating aggregate damages, all of which ultimately rely on her conclusion that the at-issue VCDs are worthless.[15] Specifically, Dr. Conti states that products "produced in accordance with cGMPs and with the manufacturer's assurance that the drugs meet legal requirements for safety, and that they have the quality, purity, identity, and strength that they are represented to possess on the FDA-approved label…are assigned a non-zero economic value by consumers and third-party payers" but that "prescription drugs that are adulterated and misbranded have no economic value."[16]

17. Dr. Conti contends that "for a consumer product to have economic value, demand for the product must exist and supply must be allowed to meet demand."[17] Dr. Conti concludes that "there is no legitimate supply curve" for "non-safety and quality compliant prescription drugs" since these drugs "should not be available for sale in the United States drug market" and that, as a result, "there is no economically determinable price for non-compliant drugs."[18] As such, Dr. Conti claims that the "'economic price' of the alleged fraud committed by the Defendants Manufacturers and Retailers is the price of each at-issue prescription sold and paid for by End-Payor and Consumers Class members at the point of sale."[19]

[15] Conti Declaration, ¶¶ 39-46, 60, 61, 64, 65, 66, 67.

[16] Conti Declaration, ¶ 7. *See also* Conti Declaration, ¶ 20.

[17] Conti Declaration, ¶ 43.

[18] Conti Declaration, ¶ 44.

[19] Conti Declaration, ¶ 56.

IV. Dr. Conti's Opinion that All of the At-issue VCDs were "Worthless" is Inconsistent with How Consumers Assess Drug Value

A. Wide Variation Across Consumers Requires Individualized Assessment of Value

18. Dr. Conti concludes that "plaintiffs paid for illegitimate products that have no economic value."[20] In this way, Dr. Conti fails to recognize that consumers already took the at-issue VCDs and derived value from them. As I will explain throughout my report, my research indicates that there exists a wide variation of perceived value across consumers which therefore requires individualized assessment of the value consumers would assign to the at-issue VCDs that they have already consumed.

19. Prescription drugs, including VCDs, are prescribed by physicians but are ultimately for the benefit of the patient/consumer. In this sense, consumers and physicians are shared decision-makers and co-creators of value when it comes to prescription drugs, including VCDs.[21]

20. In order to understand the individualized assessment of value across consumers, two interacting frameworks can be used: 1) the decision-making rules (compensatory vs. non-compensatory) to understand how consumers and physicians weigh drug features to determine drug value and 2) the message, individual differences, context, and interaction (MICI) factors that determines how healthcare decisions are made.[22] I proceed by

[20] Conti Declaration, ¶ 42.

[21] *See* Elwyn, Glyn, et al., "Shared Decision Making: A Model for Clinical Practice," *Journal of General Internal Medicine*, Vol. 27 (10), May 23, 2012, pp. 1361-1367, p. 1361; Barry, Michael J., and Susan Edgman-Levitan, P. A., "Shared Decision Making – The Pinnacle of Patient-Centered Care," *The New England Journal of Medicine*, Vol. 366 (9), 2012, pp. 780-781.

[22] *See* Keller, Punam A., and Donald Lehmann, "Designing Effective Health Communications: A Meta-Analysis of Experimental Results," *Advances in Consumer Research*, Vol. 35, 2008, pp. 117-121. ("What is the optimal design

describing how both the decision-making rules and MICI factors work together and how Dr. Conti's analysis incorrectly assesses damages by failing to properly account for these decision rules and factors, below.

B. Dr. Conti's Analysis Implicitly Relies on a Uniform Non-Compensatory Decision-Rule for Calculating Damages, Which Is Inappropriate

21. Decision-making in healthcare is a dynamic, multi-faceted psychological process which reveals that physicians and consumers make tradeoffs when choosing to prescribe or take a drug.[23] There is often a shared decision-making process among physicians and patients, which is an established phenomenon with multiple decision-rules.[24] For simplicity, I will describe two overarching decision-rules: *compensatory* and *non-compensatory*.

22. The compensatory decision-rule involves physicians and consumers placing a higher value of one drug feature to compensate for a lesser value of another feature.[25] For example,

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for health communications? A meta-analysis examines three categories of characteristics that affect response, ***context (e.g., prevention vs. detection), message factors (e.g., framing), and individual differences (e.g., gender)***." (Emphasis added.).

[23] *See* Keller, Punam A., "Social Marketing and Healthy Behavior," in *The Handbook of Persuasion and Social Marketing*, Routledge, 2015, pp. 9-38, p. 1; "[D]ecision-making during initiation of medication therapy is a dynamic, multi-faceted process. Activation and engagement, information processing, and economic factors were shown to vary over the time that medication therapy is initiated." Schommer, Jon C., et al., "Decision-Making During Initiation of Medication Therapy," *Research in Social and Administrative Pharmacy*, Vol. 10 (2), April 2014, pp. 313-327 ("Schommer et al., 2014"), p. 323.

[24] Damman, Olga C., et al., "How Do Healthcare Consumers Process and Evaluate Comparative Healthcare Information? A Qualitative Study Using Cognitive Interviews," *BMC Public Health*, Vol. 9 (423), November 2009, pp. 1-14, ("Damman et al., 2009"), p. 3.

[25] Richarme, Michael, "Consumer Decision-Making Models, Strategies, and Theories, Oh My!" *Decision Analyst,* 2005, available at https://www.decisionanalyst.com/whitepapers/decisionmaking/, accessed on January 8, 2022 ("Richarme, 2005"); "The hypothetical experimental design suggests that patients and physicians may be willing to trade off some pain relief for reduced risks for side effects; however, actual behavior may differ from their stated preferences. This is a valid concern which is difficult to verify experimentally. However, studies in patients treated with intravenous patient-controlled analgesia pumps have found that patients dosed themselves to a level of comfort (3 on the typical 0 to 10 pain scales), rather than dosing to eliminating pain completely. Findings such as these provide indirect support for the idea that patients may balance pain relief against side effects when making treatment choices." Gregorian, Jr. et al. "Importance of Side Effects in Opioid Treatment: A Trade-Off Analysis with Patients

consumers considering purchasing a daily chewable multivitamin may consider various features, including price and flavor. These two features might have equal weight (known as an *Equal Weight Compensatory* decision-rule) or have different weights for each feature (*Weighted Additive Compensatory* decision-rule).[26] An example of the latter might be to place twice as much importance on product price than on flavor preference.

23. The non-compensatory decision-rule involves physicians and consumers evaluating a specific feature of a product without regard to its other features, "and even though a product may have a very high value on one attribute, if it fails to meet the minimum acceptable value on another attribute, it is eliminated from consideration."[27,28] In the multivitamin example, a consumer who would only consider brand-name vitamins, irrespective of other features (e.g., price), would be employing a non-compensatory decision-rule. Dr. Conti's analysis applies a non-compensatory decision-rule by assuming

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and Physicians," *The Journal of Pain*, Vol. 11 (11), November 2010, pp. 1095-1108, ("Gregorian, Jr., et al., 2010"), p. 1105.

[26] Richarme, 2005; Damman et al., 2009, p. 3.

[27] Richarme, 2005.

[28] Some of the literature from the 1990s suggests that the strategy for processing information depends upon the number of alternatives. "One of the most fascinating aspects of human decision behavior is the flexibility with which individuals respond to a wide variety of task conditions…Much research suggests that your strategy for processing information will differ depending upon the number of alternatives to be considered. When faced with decision problems involving just two or three alternatives, people often use decision strategies that process all relevant information and require one to decide explicitly the extent to which one is willing to trade off less of one valued attribute or dimension…for more of another valued attributes…Such a decision process, involving the use of all relevant information and making explicit tradeoffs, is often associated with normative theories of preferential choice…When faced with more complex choice problems involving many alternatives, people often adopt simplifying (heuristic) strategies that are much more selective in the use of information. Further, the strategies adopted tend to be noncompensatory, in that excellent values on some attributes cannot compensate for poor values on other attributes." *See* Payne, John, et al., *The Adaptive Decision Maker,* Cambridge University Press 1993, pp. 1-2 Payne et al., 1993; This behavior is observed in healthcare decisions, where consumers are known to combine multiple decision models to simplify healthcare decisions. "Decision strategies are often used in combination, for example eliminating poor alternatives in an initial phase, and examining remaining alternatives in more detail in a second phase." Damman et al., 2009, p. 2; Hibbard, Judith H., and Ellen Peters, "Supporting Informed Consumer Health Care Decisions: Data Presentation Approaches that Facilitate the Use of Information in Choice," *Annual Review of Public Health*, Vol. 24, 2003, pp. 413-433, p. 416.

that the presence or potential presence of one feature—the impurity—automatically makes the at-issue products retroactively worthless regardless of any other features.

24. In the healthcare context, physicians and consumers continually evaluate multiple features when considering a drug and employ a variety of decision-making strategies in doing so.[29] For example, when considering whether to switch medications, they may weigh the uncertain side effects or interaction effects of a new drug versus the status quo of available treatments.[30] Similarly, physicians and consumers' consideration of a new drug's price and its benefits (e.g., health improvements), can also be weighed against unknown risks. Value assessment is not always binary, i.e., a "yes" (positive value) or "no" (zero value) on any one feature alone. Rather, physicians and consumers often compare across multiple features simultaneously, assigning different "weights" to different features.[31] In other words, physicians and consumers generally utilize the compensatory, rather than the non-compensatory, decision-rule.

25. This is borne out in the literature, which indicates that physicians and consumers consider and weigh multiple features when making healthcare decisions, and are thus likely to use the compensatory decision-rule to determine whether a particular drug (including VCDs)

[29] A 2012 study looking at arthritis patients notes that "arthritis patients use rules of thumb, trial and error, weigh benefits and risks, and seek more information when they receive conflicting medication information." Elstad, Emily, et al., "Patient decision making in the face of conflicting medication information," *International Journal of Qualitative Studies on Health and Well-Being,* Vol. 7 (1), August 2012, pp. 1-11 ("Elstad et al., 2012"); Schommer et al., 2014, p. 319; Damman et al., 2009, p. 2.

[30] Tong, Vivien, et al., "Consumer Interpretation of Ramipril and Clopidogel Medication Risk Information – Implications for Risk Communication Strategies," *Patient Preference and Adherence,* Vol. 9, 2015, pp. 983-988, p. 985; Elstad, et al., 2012, p. 6.

[31] Harley, Aurora, "Compensatory vs Noncompensatory: 2 Decision-Making Strategies," *Nielsen Norman Group,* October 25, 2020, available at https://www.nngroup.com/articles/compensatory-noncompensatory-decisions/, accessed on January 8, 2022; Schommer et al., 2014, p. 319; *see also* Mohamed, Ateesha Farah, et. al, "Physicians' Stated Trade-Off Preferences for Chronic Hepatitis B Treatment Outcomes in Germany, France, Spain, Turkey, and Italy," *European Journal of Gastroenterology & Hepatology*, Vol. 24 (4), 2012, pp. 419-426.

may be valuable to a particular consumer's treatment.[32] Similarly, one cannot assume physicians place an absolute value on any one particular medication or treatment because the same physician will have different value assessments for the same drug for different patients or even the same patient over time (e.g., due to declining drug efficacy over time, or due to financial concerns expressed by a patient, which may increase the weight given to the cost aspect of a treatment plan or medication).[33]

[32] "Literature shows that patients' choices are more or less influenced by *(infra)structural aspects* of health care quality (the availability of providers, the accessibility of the providers, the type and size of the providers, the availability/experience/quality of the staff, the organization of health care, the cost of treatment, and sociodemographic factors of the individual doctors), as well as by *process* (interpersonal factors, availability of information, continuity of treatment, waiting time, and the quality of treatment) and by *outcomes*…Some subgroups of patients attached more importance to measures of outcome, others to measures of process or (infra)structure." Groenewoud, Stef, et al., "What Influences Patients' Decisions When Choosing a Health Care Provider? Measuring Preferences of Patients with Knee Arthrosis, Chronic Depression, or Alzheimer's Disease, Using Discrete Choice Experiments," *Health Services Research*, Vol. 50 (6), December 2015, pp. 1941-1972, p. 1942, 1964; "Our review shows that patients' choices are determined by a complex interplay between patient and provider characteristics. A variety of patient characteristics determines whether patients make choices, are willing and able to choose, and how they choose. Patients take account of a variety of structural, process and outcome characteristics of providers, differing in the relative importance they attach to these characteristics." Victoor, Aafke, et al., "Determinants of Patient Choice of Healthcare Providers: A Scoping Review," *BMC Health Services Research*, Vol. 12 (272), August 2012, p. 1; *"*A systematic approach advocated by the World Health Organization can help minimize poor quality and erroneous prescribing. This six-step approach to prescribing suggests that the physician should (1) evaluate and clearly define the patient's problem; (2) specify the therapeutic objective; (3) select the appropriate drug therapy; (4) initiate therapy with appropriate details and consider nonpharmacologic therapies; (5) give information, instructions, and warnings; and (6) evaluate therapy regularly (e.g., monitor treatment results, consider discontinuation of the drug). The authors add two additional steps: (7) consider drug cost when prescribing; and (8) use computers and other tools to reduce prescribing errors. These eight steps, along with ongoing self-directed learning, compose a systematic approach to prescribing that is efficient and practical for the family physician. Using prescribing software and having access to electronic drug references on a desktop or handheld computer can also improve the legibility and accuracy of prescriptions and help physicians avoid errors." Pollock, Madelyn, et al., "Appropriate Prescribing of Medications: An Eight-Step Approach," *American Family of Physicians*, Vol. 75 (2), January 2007, pp. 231-236.

[33] Even further, different physicians might assess the same consumer differently as part of their evaluation of the many features they consider. The consumer and physician are co-creators of value, with the physician ascertaining whether a particular prescription will be of value for each patient. "Information on value can be helpful to physicians when talking to patients about treatment strategies. Increasingly, patients are being asked to foot a good portion of the bill for out-of-pocket costs, and copayments, and coinsurance, so I think physicians can help have better discussions with patients about treatment strategies with these kinds of value-frameworks in mind." *See* "NEJM Interview: Dr. Peter Neumann on the use of various new value-based frameworks for assessing drugs and drug prices," *New England Journal of Medicine Interview*s, December 30, 2015, available at: https://www.nejm.org/doi/10.1056/NEJMp1512009; "[D]ecision-making during initiation of medication therapy is a dynamic, multi-faceted process. Activation and engagement, information processing, and economic factors were shown to vary over the time that medication therapy is initiated." Schommer et al., 2014, p. 323.

26. Consumers employ a variety of decision rules and approaches that vary *within an individual* – a consumer may make a reflexive choice for one decision, seek a lot of information for another decision, defer to physician judgement on another decision, make a choice that contradicts their stated preferences, or even change their minds during a course of treatment.[34,35] While there are many drug features that a physician or consumer will consider when deciding to take/prescribe a drug (safety, efficacy, side effects, form factor (pill or injection), cost, dosage, et cetera), safety, efficacy, and the presence or absence of side effects are often the three most salient and critical features (particularly

[34] "In domains such as health care, such tradeoffs may be difficult and uncomfortable to make, especially if the decision situation is new and preferences must be "constructed" (Payne, Bettman, and Johnson, 1993). Decision makers are likely to employ heuristics to simplify the decision (Tversky and Kahneman, 1981), and these heuristics will be guided by the decision context. They also may refuse to make tradeoffs, because the very act of explicitly trading off the attributes (e.g. health for money) may seem unethical (Baron and Spranca, 1996); these refusals will be more likely if the tradeoff is made explicit. In addition, patients may be uncomfortable with explicit probability information because such information highlights uncertainty regarding which treatment is best, and therefore highlights the necessity of making explicit tradeoffs in choosing among available treatments." Kahn, et al., "Examining Medical Decision Making From a Marketing Perspective," *Marketing Letters,* Vol. 8 (3), July 1997, pp. 361-375, p. 367; "Individuals who face a decision problem and have a definite preference (i) might have a different preference in a different framing of the same problem, (ii) are normally unaware of alternative frames and of their potential effects on the relative attractiveness of options, (iii) would wish their preferences to be independent of frame, but (iv) are often uncertain how to resolve detected inconsistencies." Tversky, Amos and Daniel Kahneman, "The Framing of Decisions and the Psychology of Choice," *Science, New Series*, Vol. 211 (4481), January 1981, pp. 453-458, pp. 457-458; "People who hold protected values may behaviorally trade them off for other things… but they are not happy with themselves for doing so, if they are aware of what they are doing." Baron, Jonathan, and Mark Spranca, "Protected Values," *Organizational Behavior and Human Decision Processes*, Vol. 70 (1), April 1997, pp. 1-16, p. 1; "Preference reversals due to compatibility and prominence have been demonstrated with many other stimuli besides gambles (Slovic et al., 1990; Tversky et al., 1988). Reversals induced by changes in response mode have begun to appear in studies of contingent valuation as well. Brown (1984) examined dollar and rating responses of subjects' WTP for environmental amenities (air quality and forest scenic quality) and commodities (cameras, cars, stereos, and bicycles)." Irwin, Julie R., et al., "Preference Reversals and the Measurement of Environmental Values," *Journal of Risk and Uncertainty,* Vol. 6, 1993, pp. 5-6.

[35] The literature shows that consumers can make choices that contradict their stated preferences: "Past research has established that, while self-reports of purchase intentions can predict behavior, various factors affect the strength of the intentions-behavior link...The results reveal that the effect of merely asking intent to buy once is an increase in the subsequent purchase rate. The effect of repeatedly asking intent for those with low levels of intent is a decreased propensity to buy with repeated measurements. These two effects are reduced given prior experience with the product." *See* Morwitz, Vicki G., et al., "Does Measuring Intent Change Behavior?," *Journal of Consumer Research,* Vol. 20, June 1993, pp. 46-61, p. 1; "Behavioral intentions correlated significantly with behavior, although intervening events were found to attenuate the intention-behavior relation." *See* Ajzen, Icek and Martin Fishbein, "Factors Influencing Intentions and the Intention-Behavior Relation," *Human Relations*, Vol. 27 (1), 1974, pp. 1-15, p. 1.

when cost is not an issue, for example, when insurance covers the cost of medicine).[36] With a smaller subset of more salient features, consumers will tend to employ a compensatory decision-rule.[37] As each person is faced with a different set of health factors and considerations, which each have varying levels of importance for each individual, it cannot be determined which decision-rule each and every consumer will use for each context.[38] There are simply too many variables and contexts to consider. However, it is certainly the case that consumers will not all react in the same way to a change in one feature. Consumers consider different features and different weights on the same features, reflecting their experiences and preferences.

27. In this case, as I will discuss in Section IV.E, VCDs were used by a wide variety of consumers with different health profiles. Their valuations of at-issue VCDs varied depending on their individual situations. Hypertensive consumers likely valued at-issue VCDs for their positive effects on blood pressure, while those recovering from heart failure would likely place more value on the cardioprotective features. Consumers may also value the administration form of VCDs. VCDs were used as a monotherapy, a single-pill combination therapy, and in multi-pill combination therapies with various drugs. Consumers generally adhere better to single-pill therapies, which implies they value that

[36] When surveyed for topics of importance during the initiation of medical therapy, the order of most common answers among both consumers and physicians are as follows: (1) Safety, (2) Effect, (3) Cost, (4) Use, and (5) Other. Without cost considerations, safety and effect would continue to lead other considerations. Side effects are a salient factor that could be represented as either safety or effect considerations depending on the severity. Schommer et al., 2014, pp. 318-19; "Finding and Learning about Side Effects (Adverse Reactions)," *FDA,* October 5, 2021, available at https://www.fda.gov/drugs/information-consumers-and-patients-drugs/finding-and-learning-about-side-effects-adverse-reactions, accessed on January 10, 2022.

[37] Payne et al., 1993.

[38] *See* Schommer et al., 2014, p. 319; Elstad et al., 2012, p. 5; *see also* Morecroft, Charles, et al., "Patients' Evaluation of the Appropriateness of their Hypertension Management – A Qualitative Study," *Research in Social and Administrative Pharmacy*, Vol. 2 , 2006, pp. 186-211, p. 208.

administration method higher, but the choice of administration options allow consumers to select the method that best suits the consumer.[39,40] A similarly wide range of options is available in terms of dosages—oral pills range from 40 mg to 320 mg—making treatment easily tailored to the needs of the consumer.[41] Still other consumers may value the lack of side effects associated with VCDs that they experience with other medications.

28. Given this range of consumer profiles and experiences, knowledge of the presence or potential of impurities in at-issue VCDs would impact different consumers differently. Utilizing a compensatory decision-rule of drug evaluation, there would be a vast spectrum as to how individual consumers would weigh the presence or potential presence of an impurity against other beneficial features including medication efficacy, known side effects (if any), dosage form, and price. In short, the fact that different consumers have different drug features to consider, and each place different weights on different drug features, means that overall consumer evaluation of the at-issue VCDs cannot be assumed to be zero across the board, and in most, if not all, instances the value assigned would be more than zero. As one example from this case, plaintiff Samuel Cisneros testified in his

[39] Valsartan is available as both a tablet and a liquid to accommodate consumer preference. *See* "Valsartan," *MedlinePlus*, June 15, 2021, available at https://medlineplus.gov/druginfo/meds/a697015.html, accessed on January 11, 2022.

[40] *See* Zeng, Fet., et al., "Adherence and Persistence of Single-Pill ARB/CCB Combination Therapy Compared to Multiple-Pill ARB/CCB Regimens," *Current Medical Research & Opinion*, Vol. 26 (12), December 2010, pp. 2877-2887, p. 2877.

[41] "Valsartan Dosage," *Drugs.com*, available at https://www.drugs.com/dosage/valsartan.html, accessed on January 8, 2022.

deposition that [redacted].[42]

C. Dr. Conti Improperly Ignores the Message, Individual Differences, Context, and Interaction (MICI) Factors that Determine How Consumers Assess Value

1. The Message, Individual Differences, Context, and Interaction (MICI) Factors Determine How Decisions Are Made

29. Drug consumer decision-making is a function of the information provided to both the consumer and physician. Drug value, therefore, depends on how consumers process new information along 3 key factors: ***Message*** (what information consumers receive), ***Individual characteristics*** (e.g., unique medical history and health profiles), and ***Context*** (e.g., physician trust and social norms), as well as the ***Interaction*** of these three factors ("MICI").[43] I describe how these "MICI" factors contribute to consumer decision-making, below.

[42] Deposition of Samuel Cisneros, *In Re: Valsartan, Losartan, and Irbesartan Products Liability Litigation,* ("Cisneros Deposition"), pp. 73:8-77:20, 100:5-10 ("[redacted]").

[43] *See* Keller, Punam A., Donald Lehmann, "Designing Effective Health Communications: A Meta-Analysis of Experimental Results," *Advances in Consumer Research*, Vol. 35, 2008, pp. 117-121. *See also* Cole, G. E. et al., "A Message Development Tool for Health Communication: An Audience-Centered Design," *Social Marketing Quarterly*, Vol. 22 (1), 2016, pp. 3-18, Table 1. "Compared to the control condition (no financial incentive with no deadlines to enroll), more participants enrolled in the time-limited incentive programs, especially in the higher incentives and declining incentive conditions (studies 1 and 2). These effects occurred because participants in the declining incentive condition were engaged in anticipatory regret aversion." Keller, P. A., K. Hesselton, and K.G. Volpp, "Increasing Recruitment with Time Limited Financial Incentives," *Journal of the Association for Consumer Research*, Vol. 5 (3), 2020, pp. 259-270, p. 259.

(a) *Message*

30. Message describes how information is communicated to each individual decision-maker.[44] How the potential presence of impurities in the at-issue VCDs were communicated to consumers would impact their retrospective valuations of the drug. For example, a consumer who was told that their VCDs contained a probable human carcinogen without further context would likely weigh the impurity more negatively than a consumer who received the FDA's messages that the impurities at-issue, nitrosamines, are ubiquitous in everyday life (including in water, meats, dairy products, and vegetables), and that the risk to consumers of stopping the VCDs immediately before finding a replacement is higher than continuing to take them until such a replacement is found.[45,46]

31. Messaging is an important determinant in assessing value for any drug.[47] Given the ubiquity with which NDMA (or N-Nitrosodimethylamine) and NDEA (or N-

[44] Kravitz, R.L., and Bell, R.A., "Media, Messages, and Medication: Strategies to Reconcile What Patients Hear, What They Want, and What They Need From Medications," *BMC Medical Informatics & Decision Making*, Vol. 13 (55), pp. 1-8, p. 1.

[45] "FDA Statement on the FDA's Ongoing Investigation Into Valsartan and ARB Class Impurities and the Agency's Steps To Address the Root Causes of the Safety Issues," *FDA,* January 25, 2019, available at https://www.fda.gov/news-events/press-announcements/fda-statement-fdas-ongoing-investigation-valsartan-and-arb-class-impurities-and-agencys-steps, accessed on January 11, 2022; "FDA Announces Voluntary Recall of Several Medicines Containing Valsartan Following Detection of an Impurity," *FDA,* available at https://www.fda.gov/news-events/press-announcements/fda-announces-voluntary-recall-several-medicines-containing-valsartan-following-detection-impurity, accessed on December 27, 2021.

[46] While some consumers may indeed place a reduced value on products that contain probable carcinogens, consumers nonetheless do consume and / or use substances with known ties to cancer (including coffee, tobacco, alcohol, formaldehyde-treated furniture, ultraviolet rays, and processed meat, among others). *See* Booth, Stephanie, "Common Carcinogens You Should Know," *WebMD Cancer Center,* July 17, 2020, available at https://www.webmd.com/cancer/know-common-carcinogens, accessed on January 8, 2022. Consumers that knowingly use products with potential carcinogens place a higher value on the benefit they derive from those products than the potential loss in value associated with the risk of use, which consumers deem sufficiently small to justify continued use.

[47] "Consumers are paying attention to these promotions, talking to their doctors about [direct-to-consumer advertising], and even requesting prescriptions on the basis of the information conveyed […] Such advertising could damage patients' relationships with their physicians. Patients may insist on inappropriate treatments because they have seen promotional materials that they do not understand and that come from an industry that has not always

Nitrosodiethylamine) are found in everyday products, and the messages to convey this ubiquity (such as the FDA website information on NDMA/NDEA), it is unreasonable to assume that most or all consumers would believe the impurities to be of particular concern.[48] Given this assumption, such consumers would not significantly change their retrospective value assessment of at-issue VCDs due to the presence or potential presence of impurities. Consumers do not make value assessments in a vacuum. If the information regarding NDMA/NDEA's ubiquity had been reviewed by consumers who purchased the at-issue VCDs, the value those consumers placed on the at-issue product due to the impurity may not have been reduced by as great a magnitude as those who were not made aware of NDMA/NDEA's ubiquity.

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been honest about the medical value and safety of its products. Such patient requests could also direct physician attention away from other medical needs and transform the physician-patient relationship into a physician-consumer relationship […] A majority of respondents believed they would exhibit at least 1 negative reaction to their physician's denial of a prescription for a drug advertised in the general media." Bell et al., "Advertisement-Induced Prescription Drug Requests: Patients' Anticipated Reactions to a Physician Who Refuses," *The Journal of Family Practice*, Vol. 48 (6), June 1999, pp. 446-452, pp. 446, 451; "Consumers are increasingly seeking active participation in their own health care, aided in part by the wealth of information available on the Internet […] [Direct-to-consumer-advertising] brings previously untreated patients into physicians' offices where they receive a prescription for a product in the advertised class of drugs." Rosenthal, Meredith et al., "Demand Effects of Recent Changes in Prescription Drug Promotion," *Frontiers In Health Policy Research*, Vol. 6, January 2003, pp. 1-26, pp. 2, 21.

[48] "FDA Statement on the FDA's Ongoing Investigation Into Valsartan and ARB Class Impurities and the Agency's Steps To Address the Root Causes of the Safety Issues," *FDA,* January 25, 2019, available at https://www.fda.gov/news-events/press-announcements/fda-statement-fdas-ongoing-investigation-valsartan-and-arb-class-impurities-and-agencys-steps; "FDA Announces Voluntary Recall of Several Medicines Containing Valsartan Following Detection of an Impurity," *FDA,* available at https://www.fda.gov/news-events/press-announcements/fda-announces-voluntary-recall-several-medicines-containing-valsartan-following-detection-impurity, accessed on December 27, 2021.

(b) *Individual characteristics*

32. Each consumer's individual characteristics, such as their unique medical history and health profile, affect how they, and their physicians, value certain drugs.[49] Factors such as an individual's history of cancer or other co-morbidities, their proclivity towards hypertension, their age, or their access to alternative medications, affect how each consumer will value a particular drug.[50] For example, individuals with severe hypertension would likely place a high valuation on the at-issue VCDs. Similarly, individuals with no access to alternative medication, would also likely place a high valuation on the at-issue VCDs. Each individual has a unique medical history and health profile that would lead each physician and consumer to value medication, including the at-issue VCDs, differently.[51]

(c) *Context*

33. Whether a physician prescribes a medication for a particular patient depends on the balance of its benefits and potential harms for that particular patient.[52] In making such

[49] "NEJM Interview: Dr. Peter Neumann on the Use of Various New Value-based Frameworks for Assessing Drugs and Drug Price," *New England Journal of Medicine Interview*s, December 30, 2015, available at https://www.nejm.org/doi/10.1056/NEJMp1512009, accessed on January 8, 2022.

[50] *See* Long, Amanda N. and Samuel Dagogo-Jack, "Comorbidities of Diabetes and Hypertension: Mechanisms and Approach to Target Organ Protection," *The Journal of Clinical Hypertension*, Vol. 13 (4), April 2011, pp. 244-251; *See also* de Souza et al., "Hypertension in Patients with Cancer," *Aquivos Brasileros de Cardiologia,* Vol. 104 (3), March 2015, pp. 246-252.

[51] *See* Burke, Valerie et al., "Effects of a Lifestyle Programme on Ambulatory Blood Pressure and Drug Dosage in Treated Hypertensive Patients: A Randomized Controlled Trial," *Journal of Hypertension*¸ Vol. 23 (6), 2005, pp. 1241-1249.

[52] "Both patients and physicians were willing to give up a degree of pain relief to reduce side-effect risk. Among the side effects evaluated in this study, gastrointestinal side effects were consistently the leading concerns for patients and physicians in opioid treatment of acute and chronic pain. Both nausea and vomiting were at least as important as pain relief to both physicians and patients in determining preferences for opioid medications. In addition, both physicians and patients were willing to trade the greatest amount of pain relief for a reduction in the incidence of these 2 side effects. Constipation was at least as important as drowsiness and itching in determining patient and physician preference. Prior experience of or expectation of a side effect does not appear to predict preferences towards that side effect." Gregorian, Jr., et al., 2010, p. 1103.

judgments, physicians often consider additional context factors, such as the physician's personal experiences, anecdotes from other patients, peer practices, expert opinions, and insurance factors.[53] Physicians assign different values to the same drug for different patients after accounting for context factors, such as comorbidities and adherence to lifestyle modifications.[54] Consumers themselves consider context factors when considering prescriptions.[55] For example, community factors such as the economic and environmental context in which each individual operates impacts consumer health decisions such as dietary patterns, smoking, activity levels, and alcohol consumption in meaningful ways.[56]

(d) *Interaction*

34. Potential interactions among each of the three aforementioned factors (message, individual characteristics, and context) must be considered when evaluating how a consumer would retrospectively value the at-issue VCDs they took that they later learned contained or may have contained nitrosamine impurities.[57] My research indicates individual consumers will not assign the same values to health treatment options because of the interactions between

[53] "[T]here is no single pathway to health and therefore there is not a unique set of contextual characteristics that will be universally important for all health outcomes or at all stages of the outcomes." Hillemeier, Marianne M., et al., "Measuring Contextual Characteristics for Community Health," *Health Services Research*, Vol. 38 (6), December 2003, pp. 1645–1718, ("Hillemeier et al., 2003"), p. 1705.

[54] Hypertension treatment protocols advise various courses of action depending on consumer context, considering comorbidities, severity, and adherence to lifestyle modifications when recommending a prescription medication. *See* "Adult Hypertension Protocol," *Stanford Hospital and Clinics*, February 2013, available at https://www.med.stanford.edu/content/dam/sm/cerc/documents/SCC-MTM_Adult%20Hypertension%20Protocol%20Final.pdf, accessed on January 11, 2022.

[55] Hillemeier et al., 2003, p. 1650.

[56] *See* Hillemeier et al., 2003, pp. 1647, 1650.

[57] *See* Keller, Punam A., and Donald Lehmann, "Designing Effective Health Communications: A Meta-Analysis of Experimental Results," *Advances in Consumer Research*, Vol. 35, 2008, pp. 117-130. ("This study is restricted to main and ***interaction effects between categories of predictors (i.e., between message tactics and individual differences***)." p. 126 (Emphasis added.).

message, individual characteristics, and context.[58] Thus, it is invalid to assign the same fixed value to a drug for all consumers, let alone deem the drug to be viewed as worthless to all of them without accounting for the interaction between message, individual, and context, which are necessarily individualized as to each consumer.

2. Dr. Conti Improperly Ignores These MICI Factors

35. By concluding that value for at-issue VCDs went to zero for all consumers upon the identification of the impurities, Dr. Conti ignores the message, individual characteristics, context, and interaction (MICI) factors that determine how consumers make healthcare decisions. In doing so, she overlooks the inputs into the range of values that individuals may still assign to the at-issue VCDs: message (e.g., a consumer who is made aware of the VCD recalls via a message conveying the ubiquity with which NDMA/NDEA are found in everyday products might value the at-issue VCDs more than a consumer who receives a message highlighting the increased potential for cancer);[59] the individual characteristics of each consumer (e.g., an individual with severe hypertension would likely place a high valuation on at-issue VCDs); the context in which each individual operates (e.g., a patient

[58] *See* Cole, G. E. et al., "A Message Development Tool for Health Communication: An Audience-Centered Design," *Social Marketing Quarterly*, Vol. 22 (1), 2016, pp. 3-18.

[59] For example, the FDA has provided context about the ubiquity of NDMA/NDEA, stating that they are "***found in water and foods, including meats, dairy products, and vegetables***." *See* "FDA Statement on the FDA's Ongoing Investigation Into Valsartan and ARB Class Impurities and the Agency's Steps To Address the Root Causes of the Safety Issues," *FDA,* January 25, 2019, available at https://www.fda.gov/news-events/press-announcements/fda-statement-fdas-ongoing-investigation-valsartan-and-arb-class-impurities-and-agencys-steps, accessed on January 11, 2022; People who learned about the nitrosamine impurity from that source might value their VCDs more than people who learned about it from other sources that did not provide that context, for example internet or television advertisements for lawsuits regarding valsartan. "***An ad came up on Facebook***. That's how I seen [the Valsartan recall]…[***T]hat it was being recalled and there was -- there was a pending lawsuit*** against, you know, and that's how I found out about it…It's a law firm out of Florida." (Videotaped Deposition of James Lawson, *In Re: Valsartan, Losartan, and Irbesartan Products Liability Litigation*, December 16, 2021, 12:15-13:3 (emphasis added)).

compliant with non-drug regimens, such as eating a diet higher in natural foods than processed foods, may value the at-issue VCDs differently than a patient with a diet composed of more red and processed meats, which are known to have more nitrosamines); and the interaction of these factors.

D. Dr. Conti's Flawed Assumption Regarding the Value of At-Issue VCDs Ignores the Broad Set of Features that Drive the Demand for Health Care

36. Dr. Conti's implicit assumption that consumers automatically assign a $0 value to prescription drugs with a negative attribute or feature ignores the fact that consumer demand is based on consideration of a broad set of features. Negative side effects or impurities are just one feature of consideration and, historically, consumers have placed value on prescription drugs and services that have known negative side effects. Furthermore, consumers have historically taken prescription medication as desired, despite awareness of potential adverse health outcomes.

1. Consumers Have Historically Placed Value on Prescription Drugs and Services That Have Negative Side Effects

37. The literature indicates that both physicians and consumers value prescription drugs even when those drugs can have negative side effects. Despite the negative side effects, consumers continue to demand, and physicians continue to prescribe, such medication.[60]

[60] During the COVID-19 pandemic medical professionals observed patients exposing themselves to products with known risks, including in some extreme cases, bleach. "A new survey from the Centers for Disease Control and Prevention found that 4% of respondents consumed or gargled diluted bleach solutions, soapy water and other disinfectants in an effort to protect themselves from the coronavirus. Those people were among nearly 40% who reported using at least one method not recommended by the CDC in an attempt to reduce their chances of contracting the virus…The report found that people who used one of the non recommended methods also reported adverse health effects that they believed were caused by the action more frequently than those who used recommended methods." *See also* Smith-Schoenwalder, Cecilia, "CDC: Some People Did Take Bleach to Protect From Coronavirus," *U.S. News*, June 5, 2020, available at https://www.usnews.com/news/health-news/articles/2020-06-05/cdc-some-people-did-take-bleach-to-protect-from-coronavirus, accessed on January 10, 2022.

38. As an example, Accutane, or isotretinoin (the generic form), is a medication used to treat severe cystic acne that has not responded to other forms of treatment.[61] While the drug is intended to target acne, it has a number of potentially serious side effects, including: eye irritation; skin infection; bone tenderness; vision loss; birth defects (in pregnant women); and skin inflammation.[62] In fact, Accutane was at the center of a decade-long litigation involving "thousands of cases in which plaintiffs claim the prescription acne medication caused inflammatory bowel disease (IBD)."[63]

39. Despite the negative side effects that consumers can encounter with Accutane (and isotretinoin) use, consumers consider its benefits (reduction in acne) to outweigh the potential costs (negative side effects), and physicians prescribe it in order to give consumers the benefits they seek despite the risks. In other words, for some consumers, even though the drug has a feature that would be weighted as a negative (side effects), on balance when weighed against other features (such as efficacy in treating acne), the drug still has an overall net positive value for those consumers who decide to take it.

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[61] "Accutane 40 MG Capsule Retinoids and Derivatives (Systemic) - Uses, Side Effects, and More," *WebMD.com,* 2021, available at https://www.webmd.com/drugs/2/drug-6661/accutane-oral/details, accessed on January 10, 2022; *See* Nguyen, Danny, "Looking for Alternatives to Accutane? Here Are 5 Options," *GoodRx*, February 24, 2021, available at https://www.goodrx.com/conditions/acne/accutane-alternatives-for-acne, accessed on January 10, 2022.

[62] "Accutane (Isotretinoin) Capsules," *FDA Drug Label*, available at https://www.accessdata.fda.gov/drugsatfda_docs/label/2002/18662s051lbl.pdf, accessed on January 10, 2022; *See* Leon, Steven, "Optimizing Isotretinoin Treatment: Keys to Successful Prescribing and Management," *Practical Dermatology*, April 2015, available at https://practicaldermatology.com/articles/2015-apr/optimizing-isotretinoin-treatment-keys-to-successful-prescribing-and-management, accessed on January 10, 2022.

[63] Stone, Kaitlyn E. and Abigail M. Luhn, "Hierarchy of Scientific Evidence Reigns Supreme: NJ Appellate Division Affirms Exclusion of Experts in Accutane Litigation," *The National Law Review,* Vol. 10 (35), February 2020, pp. 1-3, pp. 1-2; "Most Accutane lawsuits claim the drug caused Crohn's disease and other inflammatory bowel disorders. A court dismissed the majority of the more than 7,000 lawsuits filed against Swiss manufacturer Roche in 2014. The New Jersey Supreme Court dismissed another 500 lawsuits in 2018." *See* Compton, Kristin, "Accutane Lawsuits," *Drugwatch*, March 25, 2021, available at https://www.drugwatch.com/accutane/lawsuits/, accessed on January 10, 2022.

40. Other examples of consumers valuing medicine with negative side effects include demand for high-risk drugs, such as those that are newer entrants into the marketplace and / or drugs that have FDA black box warnings. These black box warnings for drugs and medical devices are the FDA's most stringent warnings, alerting "the public and health care providers to serious side effects, such as injury or death."[64] A 2002 study looking at withdrawals for prescription medication points out that recently approved drugs may be more likely to have unrecognized adverse drug reactions ("ADRs") than established drugs, and notes that serious ADRs commonly emerge after the FDA approval process.[65] Oftentimes, the safety of new medications will not be known with any certainty until a particular drug has been on the market for several years.[66] The study points out that consumer exposure to new drugs with unknown toxic effects "may be extensive," with nearly 20 million U.S. consumers having taken "at least 1 of the 5 drugs withdrawn from the market between September 1997 and September 1998."[67] Despite these warnings and potentially negative side effects, there is still a demand for new prescription drugs and prescription drugs with black box warnings, indicating that such drugs retain value.

41. Consumers also regularly expose themselves to cancer risks for just the benefit of appearance. UV tanning beds offer no direct health benefits but pose significant cancer

[64] "Black Box Warning" *Drugwatch.com*, April 13, 2020, available at https://www.drugwatch.com/fda/black-box-warnings/, accessed on January 11, 2022.

[65] Lasser, K., Allen, P., Woolhandler, S., et al., "Timing of New Black Box Warnings and Withdrawals for Prescription Medications," *Journal of the American Medical Association*, Vol. 287 (17), May 2002, pp. 2215-2220, ("Lasser and Woolhandler, 2002") p. 2215.

[66] Lasser and Woolhandler, 2002, p. 2215.

[67] Lasser and Woolhandler, 2002, p. 2215.

risks for users.[68] Despite significant investment in health education, consumers still value the treatment and are willing to pay for it, with tanning salons generating $3.7 billion in revenue in 2021.[69] As these few examples demonstrate, a product or service having one negatively weighted feature—even when that feature is an unknown but potential risk of cancer—does not make the product or service automatically "worthless" to all consumers.

2. Consumers Have Historically Taken Prescription Drugs As Desired, Rather Than As Prescribed, Despite Awareness of Potential Adverse Health Outcomes

42. Consumers continually make risk trade-offs when considering their healthcare. Medication adherence is a revealed preference indicator of value and is defined by the World Health Organization as "the degree to which the person's behavior corresponds with the agreed recommendations from a health care provider."[70]

43. Adherence to medication protocols is often a critical aspect in healthcare, particularly in the treatment of chronic conditions such as diabetes and hypertension.[71] Consequences of non-adherence can include the worsening of patients' conditions, an increase in comorbid diseases, increased patient healthcare costs, and even death.[72] Despite the importance of

[68] Karagas, M. R. et al., "Use of Tanning Devices and Risk of Basal Cell and Squamous Cell Skin Cancers." *Journal of the National Cancer Institute,* Vol. 94 (3), February 2002, pp. 224-226.

[69] "Tanning Salons in the US – Market Size 2005-2027," *IBISWorld*, November 1, 2021, available at https://www.ibisworld.com/industry-statistics/market-size/tanning-salons-united-states/, accessed on January 10, 2022.

[70] Dobbels et al., "Growing Pains: Non-adherence with the Immunosuppressive Regimen in Adolescent Transplant Recipients," *Pediatric Transplantation*, Vol. 9 (3), June 2005, pp. 381-390, p. 381.

[71] *See* Chisholm-Burns, Marie A. and Christina A. Spivey, "The 'cost' of Medication Nonadherence: Consequences We Cannot Afford to Accept," *Journal of the American Pharmacists Association,* Vol. 52 (6), 2012, pp. 823-826 ("Chisholm-Burns et al, 2012"), p. 823; *See also* Burnier, Michel and Brent M. Egan, "Adherence in Hypertension - A Review of Prevalence, Risk Factors, Impact, and Management," *American Heart Association - Circulation Research*, Vol. 124 (7), March 2019, pp. 1124-1140.

[72] Chisholm-Burns et al, 2012, pp. 823.

medication adherence, non-adherence is a major problem, with the World Health Organization noting that 50% of those with chronic illnesses do not adhere to their medications.[73]

44. Consumer non-adherence "varies between and within individuals, as well as across time, recommended behaviors, and diseases."[74] The literature reports that general long-term compliance rates range roughly from 33% to 69%.[75] Non-adherence can occur when the medication regimen is complex, and may be more likely to occur, for example, when the drug protocol involves administration of numerous medications at frequent or unusual times during the day. In a systematic review of hypertensive consumers, researchers found that consumers undergoing single-pill combination therapy were more likely to adhere to their protocols than those receiving therapy involving multiple pills.[76]

45. Medication non-adherence, whether arising out of awareness or negligence, is a constant issue across diseases and is a key indicator that consumers put their own personal value on prescribed drugs:

> *Non-adherence is a very common phenomenon in all patients with drug taking behavior. Complexity of adherence is the result of an interplay of a range of*

[73] Chisholm-Burns et al., 2012, p. 823; World Health Organization, "Chapter 2: The Magnitude of the Problem of Poor Adherence," *Adherence to Long-Term Therapies - Evidence for Action*, 2003.

[74] Sewitch et al., "Medication Non-adherence in Women with Fibromyalgia." *Rheumatology*, Vol. 43 (5), May 2004, pp. 648-654, p. 648.

[75] Sackett, D.L., John C. Snow. "The Magnitude of Compliance and Non Compliance." In Haynes NRB, Taylor DW, Sackett DL, eds. *Compliance in Health Care*. Baltimore: John Hopkins University Press; 1979, pp. 11-22, pp. 17-18.

[76] Parati et al., "Adherence to Single-Pill Versus Free-Equivalent Combination Therapy in Hypertension," *Hypertension,* Vol. 77, February 2021, pp. 692-705.

factors including patient views and attributes, illness characteristics, social contexts, access and service issues.[77]

Patient adherence, or non-adherence, is one indicator of a patient's valuation of a particular prescription medication.

E. Real-world Evidence Indicates that the At-Issue VCDs Held Value

1. The Positive Attributes of At-Issue VCDs Differed Among Consumers

46. The benefits of VCDs differed among consumers. Some consumers likely benefited more than others as a result of taking at-issue VCDs, and therefore many consumers may still assess significant positive value for the at-issue VCDs.

47. The consumer health profile informs how consumers value the medication they take. While the impurities in or potentially in the at-issue VCDs may present some perceived risks to some consumers, the underlying risks of the consumer's health need to be considered in the evaluation of the value placed on the at-issue VCDs. In cases involving use of VCDs, consumers often present a health profile that has elevated risk beyond being hypertensive. VCDs are approved by the FDA for treatment of high blood pressure, heart failure, and to reduce risk of death in consumers who have developed congestive heart failure following a heart attack.[78]

[77] Beena, Jimmy and Jimmy Jose, "Patient Medication Adherence: Measures in Daily Practice," *Oman Medical Journal*, Vol. 26 (3), May 26, 2011, pp. 155-159 ("Beena and Jimmy, 2011") p. 156.

[78] "Losartan vs Valsartan – What's the Difference Between Them?" *Drugs.com*, July 15, 2021, available at https://www.drugs.com/medical-answers/difference-between-losartan-valsartan-3504796/, accessed on January 10, 2022.

48. Hypertension is highly prevalent in the United States, present in 45.4% of adults in 2018 with increasing incidence among older populations.[79] Such a large portion of the population encompasses a wide range of health profiles and comorbidities. Therefore, prescriptions of VCDs for hypertension also cover a wide variety of health profiles with differing consumer valuations of treatment. Older consumers facing more serious health risks may value the therapeutic benefits of VCDs more highly than their younger counterparts with milder hypertension. This is particularly true for consumers using VCDs for other purposes. Those taking VCDs as a treatment for heart failure, for example, are facing much more serious health outcomes, than consumers taking VCDs for mild hypertension. Likewise, consumers taking VCDs who have experienced adverse reactions or severe side effects in response to alternative medications would value the at-issue VCDs more highly due to the absence of such adverse reactions or side effects.

49. Furthermore, in my opinion the valuation of at-issue VCDs will vary across demographics. As discussed in Section IV.C, individual characteristics are determinants of the value of a drug, so the individual characteristics of the consumers are determinants of the value of at-issue VCDs. The application of a uniform valuation to at-issue VCDs is therefore inaccurate because it does not consider the unique medical history and health profiles of the consumers using the at-issue VCDs at the time of recalls.[80]

50. Differing valuation of medication among a population is common across all medications and is clearly illustrated through medication non-adherence. As discussed above in

[79] Ostchega et al., "Hypertension Prevalence Among Adults Aged 18 and Over: United States, 2017-2018," *NCHS Data Brief*, April 2020, ("Ostchega et al., 2020"), p. 1.

[80] Ostchega et al., 2020, p. 1.

Section IV.D, the degree to which a consumer adheres to the medication given to them reflects their views on the value of the medication.[81] Those with chronic illnesses, like hypertension, are particularly likely to display non-adherence, especially since there are often no unpleasant symptoms associated with the diagnosis.[82] However, ARBs (angiotensin receptor blockers) like VCDs have been shown to have a higher adherence rate than other hypertensive therapies, showing that they are generally seen as higher value by the consumers.[83]

2. Consumers Would Likely Assess the Impact of the Impurities in At-Issue VCDs Differently

51. There would likely be a broad spectrum of consumer's perceived assessment of the change in value of at-issue VCDs as a result of the presence or potential presence of the impurities. As described further in Section IV.F, it is possible that some consumers might retrospectively view the VCDs they purchased as significantly less valuable due to the presence or potential presence of impurities. At the same time, however, there are likely many consumers for whom the impurities had a de minimis impact on assessed value. For example, consumers, who have a serious condition that was treated by at-issue VCDs, are less likely to view those VCDs as worthless after learning of the impurities.

52. The statements of consumers, particularly those involved in litigation, regarding their retrospective valuation of at-issue VCDs may not be reliable measures of even individual

[81] Beena and Jimmy, 2011.

[82] Hamdidouche et al., "Drug Adherence in Hypertension: From Methodological Issues to Cardiovascular Outcomes," *Journal of Hypertension*, Vol. 35 (6), January 2017, pp. 1133-1144, p. 1133.

[83] ARBs have been shown to have a 20% non-adherence rate compared to 30% nonadherence for diuretics. Chang et al., "National Rates of Nonadherence to Antihypertensive Medications Among Insured Adults With Hypertension, 2015," *Hypertension*, Vol. 74 (6), December 2019, pp. 1324-1332, p. 1330.

value assessments, much less population-wide value assessments. Nonetheless, testimony of several consumer-plaintiffs in this case corroborates this post-awareness value for the at-issue VCDs. For example, Samuel Cisneros acknowledges that [redacted]."[84] Additionally, many other consumers admitted that even with their current knowledge of the impurities, the VCDs they took were effective in treating their hypertension.[85]

53. Depositions provide numerous additional examples of consumers whose lifestyles present risks which may alter their assessment of at-issue VCDs and cast doubt on their stated retrospective value assessments. Multiple depositions reveal individuals with diets already

[84] Cisneros Deposition, pp. 73:8-74:20, 100:9-10.

[85] *See* [redacted]

rich in nitrosamines such as red meat, bacon, and dairy.[86] [redacted], and many other consumer-plaintiffs likewise had a history of smoking[87] and other health risks that would be higher than the risk presented by the impurities.[88] For example, the FDA acceptable limit of NDMA is 96 nanograms per day, which is what was used to set the interim NDMA limits.[89] Cooked bacon has been measured consistently around 10 micrograms (or 1000 nanograms) of NDMA per 100 grams.[90] A serving of bacon is 15 grams.[91] Therefore, a single serving of cooked bacon

[86] *See* [redacted]

[87] Other putative class representatives that have a history of smoking include [redacted].

[88] [redacted] The CDC has estimated that 40% of all cancer cases in the U.S. are related to tobacco use, and that of the 36 million smokers in the U.S., six million will die prematurely from cancer. "Cancers Linked To Tobacco Use Make Up 40% Of All Cancers Diagnosed in the United States," *Centers for Disease Control and Prevention*, November 10, 2016, available at https://www.cdc.gov/media/releases/2016/p1110-vital-signs-cancer-tobacco.html, accessed on January 11, 2022.

[89] "FDA Updates Table of Interim Limits for Nitrosamine Impurities in ARBs," *FDA*, February 28, 2019, available at https://www.fda.gov/drugs/drug-safety-and-availability/fda-updates-and-press-announcements-angiotensin-ii-receptor-blocker-arb-recalls-valsartan-losartan#interimlimits2, accessed on January 9, 2022.

[90] Lijinsky, William, "*N*-Nitroso Compounds in the Diet," *Mutation Research/Genetic Toxicology and Environmental Mutagenesis*, 1999, Vol. 443 (1–2), pp. 129-138, p. 129.

[91] Rinkunas, Susan, "How Much Bacon is Too Much Bacon?" *The Cut*, September 8, 2016, available at https://www.thecut.com/2016/09/how-much-bacon-can-i-eat.html, accessed on January 10, 2022.

would represent roughly 150 nanograms of NDMA, about 50% higher than the acceptable limit of NDMA laid out by the FDA. Other products such as meats, dairy, and vegetables have been demonstrated to contain NDMA.[92] Dietary choices of the individual can reveal their risk tolerance for nitrates may already be much higher than recommended intake, and potentially reflect how they evaluate NDMA exposure with much greater accuracy than their retrospective statements as litigants.

54. Alternatively, there are other consumers who have very controlled diets and lifestyles in terms of health risk. Depositions reveal that some consumers made dietary and lifestyle changes to manage hypertension, lowering their nitrosamine intake in the process.[93] These consumers are focused on maintaining healthy lifestyles and may react differently in their evaluation of impurities or potential impurities in at-issue VCDs.

55. In sum, consumers each have their own preferences and health profiles so it certainly is not the case that all consumers would assign a value uniformly to any medication, including the at-issue VCDs.

3. Responses to the Recalls of VCDs by the FDA and Consumers Indicate VCDs Provided Significant Value

56. The FDA recommended at the time of the recalls that consumers continue taking the recalled VCDs until they could find a replacement, explaining that "[b]ecause valsartan is

[92] "FDA Statement on the FDA's Ongoing Investigation Into Valsartan and ARB Class Impurities and the Agency's Steps To Address the Root Causes of the Safety Issues," *FDA,* January 25, 2019, available at https://www.fda.gov/news-events/press-announcements/fda-statement-fdas-ongoing-investigation-valsartan-and-arb-class-impurities-and-agencys-steps, accessed on January 11, 2022.

[93] *See* [redacted].

used in medicines to treat serious medical conditions, patients taking the recalled valsartan-containing medicines should continue taking their medicine until they have a replacement product."[94]

57. On February 28, 2019, the FDA posted its interim limits for NDMA, NDEA and NMBA (N-Nitroso- N-methyl-4-aminobutyric acid) in ARBs.[95] The calculated limit risk is 1 additional case of cancer per 100,000 people at over 70 years of usage.[96] The estimated risk of the affected VCDs is 1 additional case of cancer per 8,000 from four years of daily usage at the highest dosage.[97] Despite setting these limits, the FDA recognized the value of ARB treatment and released official guidance to allow for distribution of VCDs that exceed that limit if it is necessary to do so in order to prevent a shortage:

> *Any API [Active Pharmaceutical Ingredient] batch found to contain levels of nitrosamine impurities above the recommended AI [Acceptable Intake] should not be released by the API manufacturer for distribution unless,*

[94] "FDA Announces Voluntary Recall of Several Medicines Containing Valsartan Following Detection of an Impurity," *FDA,* July 13, 2018, available at https://www.fda.gov/news-events/press-announcements/fda-announces-voluntary-recall-several-medicines-containing-valsartan-following-detection-impurity, accessed on December 27, 2021.

[95] "FDA Updates and Press Announcements on Angiotensin II Receptor Blocker (ARB) Recalls (Valsartan, Losartan, and Irbesartan)," *FDA*, February 28, 2019, available at https://www.fda.gov/drugs/drug-safety-and-availability/fda-updates-and-press-announcements-angiotensin-ii-receptor-blocker-arb-recalls-valsartan-losartan, accessed on January 11, 2022.

[96] "FDA Updates and Press Announcements on Angiotensin II Receptor Blocker (ARB) Recalls (Valsartan, Losartan, and Irbesartan)," *FDA*, February 28, 2019, available at https://www.fda.gov/drugs/drug-safety-and-availability/fda-updates-and-press-announcements-angiotensin-ii-receptor-blocker-arb-recalls-valsartan-losartan, accessed on January 11, 2022.

[97] "Laboratory Analysis of Valsartan Products" *FDA*, available at https://www.fda.gov/drugs/drug-safety-and-availability/laboratory-analysis-valsartan-products, accessed on January 11, 2022.

with prior FDA agreement, the API is needed to prevent or mitigate a shortage of a drug.[98]

58. For example, in 2019 the FDA allowed losartan on the market with an NMBA impurity below 9.82 ppm, when the official limit was 0.96ppm.[99]

59. These actions demonstrate that the FDA views drugs with nitrosamine impurities as having value because it recommended that consumers continue to take them until a replacement could be obtained and it allowed for violation of its own regulatory limits to achieve optimum health outcomes for the market.[100] In other words, the value of a treatment is not binary depending on the presence or absence of a nitrosamine impurity.

60. Consistent with the FDA guidance, physicians recommended, and consumers decided to continue taking the at-issue VCDs until they found replacement products. This illustrates that despite the alleged potential increased risk of cancer, consumers attributed *some* non-zero value to the at-issue VCDs because they were effective treatments, had minimal to no side effects, were easy to adhere to, and/or any number of other positive features. Consistent with a compensatory decision-rule, the defined risk of the at-issue VCDs may be significantly smaller than the risks presented by untreated hypertension, even with the presence of the impurities. This type of tradeoff is common in the healthcare industry as it

[98] "Control of Nitrosamine Impurities in Human Drugs: Guidance for Industry," *FDA*, February 2021, available at https://www.fda.gov/media/141720/download, accessed on January 9, 2022.

[99] "FDA Updates Table of Interim Limits for Nitrosamine Impurities in ARBs," *FDA*, February 28, 2019, available at https://www.fda.gov/drugs/drug-safety-and-availability/fda-updates-and-press-announcements-angiotensin-ii-receptor-blocker-arb-recalls-valsartan-losartan#interimlimits2, accessed on January 9, 2022.

[100] "FDA Updates Table of Interim Limits for Nitrosamine Impurities in ARBs," *FDA*, February 28, 2019, available at https://www.fda.gov/drugs/drug-safety-and-availability/fda-updates-and-press-announcements-angiotensin-ii-receptor-blocker-arb-recalls-valsartan-losartan#interimlimits2, accessed on January 9, 2022.

is common for physicians to prescribe medications with risks, particularly among older populations.[101]

61. At-issue VCDs also did not immediately lose their value to physicians following their voluntary recalls. For recalled drugs, the risk of quitting, even for a few days, may be far greater than the risk posed by a minute amount of a toxic substance. For example, in response to the recalls of VCDs, Steven Nissen, cardiologist at the Cleveland clinic, commented:

> *If you stop your blood pressure medication, your blood pressure can spike. That can increase your risk for a stroke or a heart attack. It can be anxiety-provoking to continue taking a recalled medication. But the cancer risk posed by nitrosamines is theoretical. You don't want your blood pressure to go up precipitously while you're waiting to get a doctor's appointment.* [102]

62. Mark Benson, a cardiologist at Beth Israel Deaconess Medical Center in Boston, also weighed in, saying that he has "…had patients who took valsartan for years, stopped due

[101] For example, more than 20% of older adults are chronically using at least one unsafe maintenance medication. Lauffenburger et al., "Rationale and Design of the Novel Uses of Adaptive Designs to Guide Provider Engagement in Electronic Health Records (NUDGE-EHR) Pragmatic Adaptive Randomized Trial: A Trial Protocol," *Implementation Science*, Vol. 16 (9), January 2021, p. 2.

[102] Harrar, Sari, "Tainted Drugs: Are Our Prescriptions Safe?" *AARP*, December 9, 2019, available at https://www.aarp.org/health/drugs-supplements/info-2019/drug-recall-what-to-do.html, accessed on December 21, 2021.

to the recall, and their blood pressure became poorly controlled. That shouldn't happen."[103]

63. There is also ample consumer testimony that corroborates this post-awareness value for the at-issue VCDs. For example, Samuel Cisneros acknowledges that [redacted]."[104] Other consumers demonstrated implicit value for the at-issue VCDs considering they, for at least a short while, continued to take the at-issue VCDs in their possession after becoming aware of the recalls.[105]

64. These examples serve as informative case studies on the value consumers may place on the at-issue VCDs after the recalls. As some consumers continued to take the at-issue VCDs after being informed of the recalls, their decision to continue consumption indicates that they still assessed some positive value to the at-issue VCDs.[106]

[103] Harrar, Sari, "Tainted Drugs: Are Our Prescriptions Safe?" *AARP*, December 9, 2019, available at https://www.aarp.org/health/drugs-supplements/info-2019/drug-recall-what-to-do.html, accessed on December 21, 2021.

[104] Cisneros Deposition, pp. 73:8-74:20, 100:9-10.

[105] *See* [redacted]

[106] I understand that consumers were unable to fill prescriptions for the at-issue VCDs shortly after the recall dates and that certain consumers who retained a prescription for the at-issue VCDs continued to consume them, while others disposed of them. I further understand that those consumers who continued to fill prescriptions after the recall date were generally consuming VCDs that did not contain impurities. "Product Recalls, Including Removals and Corrections: Guidance for Industry," *FDA*, March 2020, available at https://www.fda.gov/media/136987/download, accessed on January 11, 2022; "Recalls of Angiotensin II Receptor Blockers (ARBs) including Valsartan, Losartan, and Irbesartan," *FDA*, February 3, 2021, available at https://www.fda.gov/drugs/drug-safety-and-availability/recalls-angiotensin-ii-receptor-blockers-arbs-including-valsartan-losartan-and-irbesartan, accessed on January 11, 2022.

F. Dr. Conti Incorrectly Assesses Damages for the Consumer Class

65. By assuming the value of all the at-issue VCDs is zero, Dr. Conti's analysis relies on a non-compensatory decision-rule for calculating damages. Dr. Conti does not provide any evidence that such a decision-rule is appropriate in this matter, and it is my opinion that it is not the appropriate decision-rule to apply here.[107] Dr. Conti's damages calculation suggests that the entirety of the value generated from the at-issue VCDs over the at-issue period was retroactively destroyed for all consumers by one negative feature—the presence or potential presence of the impurities. This approach is overly simplistic and does not account for the realities of the healthcare decision making process.

66. Instead of evaluating any true potential loss in value that resulted from the impurities, Dr. Conti assumes that no trade-off would have occurred for any consumer had the presence of impurities been identified earlier, since there would be no supply of at-issue VCDs. This is shown in Figure 2 of Dr. Conti's declaration, where she removes the supply curve and claims that "there is no economically determinable price for non-compliant drugs."[108] Dr. Conti's analysis is not consistent with the goal of attempting to determine potential economic damages to consumers because it ignores the fact that consumers did purchase the at-issue VCDs and, to the extent there would have been an impact in consumers' retrospective evaluation of the at-issue VCDs upon learning about the impurities, how the change in demand for at-issue VCDs due to the impurities would appear in the demand

[107] Instead of providing such evidence, Dr. Conti relies on the argument that "assigning a non-zero value to non-safety and quality compliant products is perverse. To do so would be to incentivize and legitimize cheating and non-compliance by manufacturers and other members of the United States pharmaceutical supply chain, and would undermine the substantial investments made by the government and private parties to protect the wellbeing of American patients." Conti Declaration, ¶ 45.

[108] Conti Declaration, ¶ 44.

curve. Put simply, Dr. Conti appears to analyze an alternative world in which the at-issue VCDs could not have been sold, and therefore could not have been priced, rather than addressing the value of the at-issue VCDs in the actual world in which consumers purchased and consumed the at-issue VCDs.

67. In reality, consumers were allegedly supplied VCDs that contained or may have contained impurities, used them, and realized a therapeutic benefit from them. To understand the potential economic damages, if any, to consumers in this real-world scenario, one would need to adjust the demand curve to reflect the fact that different consumers might value VCDs containing or potentially containing impurities differently than VCDs without impurities (considering that at the time of purchase consumers were not aware of any impurities). In conducting this analysis, one would need to examine the idiosyncratic impact of the impurities on demand for at-issue VCDs. Specifically, it is prudent to analyze how the spectrum of consumers would distinctively react to the presence of or potential presence of impurities in the at-issue VCDs that they purchased.

68. According to Dr. Conti's analysis, the entire spectrum of consumers would view the at-issue VCDs that they purchased as worthless, but as my analysis shows, this is not the case. In fact, as I described in Section IV.E, evidence demonstrates that there remained significant positive value for the at-issue VCDs, and the precise retrospective valuation would differ from consumer to consumer across the entire spectrum of consumers.

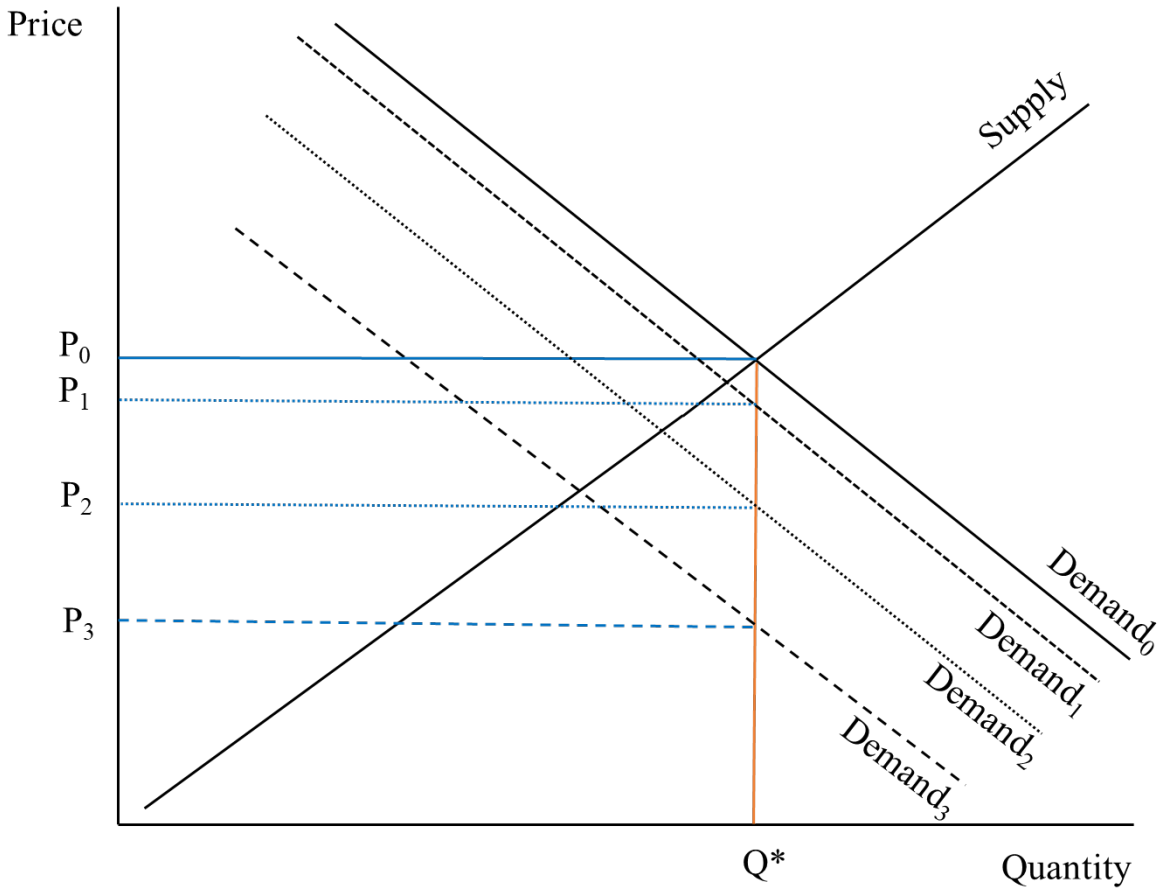
69. Research on consumer decision-making in healthcare contexts indicates that some consumers would experience minimal to no impact on demand due to the impurities, some would experience a moderate demand shift, and some would experience a large demand

shift. What ultimately determines consumers' shift in demand is their individualized assessments of value of the VCDs they purchased and the assessed negative value of the impurities. As discussed in Section IV.D, there are many features relevant to understanding the impact on demand for different types of consumers, and those features vary from one consumer to the next, including assessed benefits from at-issue VCDs, risk tolerances, lifestyle choices, and assessment of risks, among others.

70. More specifically, some consumers may have placed a high value on the at-issue VCDs relative to any negative assessments associated with the impurities. For example, some consumers might have significant health consequences if they did not take the at-issue VCDs and/or lack good alternatives to the at-issue VCDs due to adverse reactions or side effects, and would not have significant negative reactions to the impurities (e.g., consumers who will not reach the FDA's maximum allowable threshold and consumers who already intake significant quantities of NDMA/NDEA in their daily routine and are likely to be less worried or not worried about the consequences). Alternatively, some consumers may have placed a low value on the at-issue VCDs relative to any negative assessments associated with the impurities. For example, some consumers may not have faced as serious health consequences if they stopped taking the at-issue VCDs and potentially would have feared significant negative reactions to the impurities.

71. With this broad spectrum of consumer reactions in mind, instead of simply making the supply curve of at-issue VCDs disappear, Dr. Conti should have examined the change in demand for VCDs with or that may contain impurities as informed by the compensatory decision-rule and MICI factors that reflects actual consumer behavior in healthcare settings, as shown by way of example in the figure, below.

Consumer Demand During At-issue Period
Examples of Varying Impact on Demand



72. As shown in the figure above, there existed some original supply and demand curve (denoted by "$Demand_0$" and "Supply"), which resulted in an equilibrium price, P_0, and equilibrium quantity, Q*. Instead of removing the supply curve, and assuming zero demand, it is more appropriate to envision how each consumer's demand would shift due to knowledge of the presence (or potential presence) of impurities. For illustration purposes, I provide examples of how demand could shift, though in reality there is a spectrum of responses for the wide variety of consumers. It follows that demand for the at-issue VCDs is represented by "$Demand_1$"/"$Demand_2$"/"$Demand_3$" which can be evaluated

through the compensatory decision-rule and MICI factors I described in Sections IV.B and IV.C.[109]

73. The value of at-issue VCDs follows by examining the price consumers actually paid for the at-issue VCDs compared to the price they would have paid had they known about the impurities or potential for the impurities. Even if the at-issue VCDs would not have been sold if the impurities had been known at the time of sale, the fact is consumers did consume Q* VCDs. Therefore, the potential economic harm resulting from the impurities should be based on the value of Q* and prices associated with each of the consumers' individualized valuations (ranging from P_1 to P_3) of VCDs after accounting for changes in consumer demand resulting from consumer knowledge of the impurities. As shown in the figure above, this impact on consumer demand could vary significantly throughout the spectrum of consumers and this would ultimately have large impact on the resulting potential economic harm.

74. For Dr. Conti to arrive at the damages conclusions that she does while using the more appropriate compensatory decision-rule, she would need to assume that the price is zero at the point in which demand for at-issue VCDs intersects with Q*, the sales of at-issue VCDs that took place in reality. This is theoretically possible if the impurities are sufficiently impactful on the demand of the at-issue VCDs, but in practical terms is highly implausible and simply does not fit the circumstances of the recalled VCDs. As I described in Section IV.E, evidence demonstrates that there remained significant value for the at-issue VCDs. Further, even if it were assumed that some consumers might no longer

[109] In fact, some consumers may have experienced no impact on their demand and, therefore, their demand for the VCDs with impurities is represented by "$Demand_0$."

value the at-issue VCDs or might assign significantly reduced value to them, such consumer assessment certainly cannot be seen as a universal or majority value assessment, and therefore does not support a uniform inference that all individual consumers would consider the at-issue VCDs worthless. As such, by attributing zero economic value to the at-issue VCDs for all consumers, Dr. Conti has ignored the ways in which consumers and physicians make evaluations in health care settings.

75. Further, where Dr. Conti professes her ability to assign damages to Retailer and Wholesaler Defendants for "unjust enrichment" by benefits conferred upon those defendants by consumers, her proposed methodology ignores the individual assessment required to determine the value (i.e., benefit) any one consumer derived from the at-issue VCDs at any point in time.

Signed on the 12th day of January 2022.

Punam A. Keller

Appendix A

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Institution	Degree	Date	Field
Elphinstone College, Bombay University, India	BA	1977	Economics & Statistics
Bajaj Institute of Management Bombay University, India	MBA	1979	Marketing
Northwestern University	Ph.D.	1984	Marketing

ACADEMIC POSITIONS

September 1983 - August 1987	Assistant Professor, New York University
September 1987 - June 1995	Assistant/Associate Professor, Columbia University
July 1993 - June 1995	Visiting Associate Professor, Stanford University
July 1995 - April 1997	Associate Professor, University of North Carolina
May 1997 - June 1998	Visiting Associate Professor, Duke University, Adjunct Faculty, Duke Medical Center
July 1998 – May 2004	Professor, Tuck School, Dartmouth College, Adjunct Faculty, Dartmouth-Hitchcock Medical Center
June 2002 – June 2018	Member, Cancer Control Research Program, Norris Cotton Cancer Center, Lebanon, NH.
June 2002 – present	Charles Henry Jones Third Century Professor of Management

July 2015 – June 2018	Associate Dean for Innovation and Growth
July 2018 – July 2020	Deputy Dean
August 2020 – July 2021	Senior Associate Dean for Innovation and Growth
August 2021 - Present	Senior Associate Dean for Advancement and Tuck-Dartmouth Programs

TEACHING EXPERIENCE

MBA Program: Marketing Management, Marketing Strategy, Consumer Behavior, and Social Marketing.
Ph.D. Program: Seminar in Consumer Behavior.
Executive Program: Marketing Management, Marketing Strategy, Social Marketing, and Services Marketing.

RESEARCH INTERESTS

Application of social marketing principles and behavioral theory to consumer and employee wellness programs.

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WORKING PAPERS

Chen E., P. A. Keller et al., "Evaluation of an Intervention to Improve Patients' Self-Management of Heart Failure," Working Paper.

Keller, A. P. and Annamaria Lusardi, "Message Design to Change Behavior," Working Paper.

Lee, Pamela, C. Gaffney, A. L. Olson, and P. A. Keller, "It's the Genes. There is Not Much We Can do About That: Mothers' Perceptions of Factors that Influence Childhood Overweight," Working Paper.

Keller, Anand, P. "Using Need for Control to Change Preventative Health Behaviors," Working Paper.

Keller, A. P., and A. L. Olson, "Negative Emotions and Coping Health Appraisal," Working Paper.

Keller, A. P. and L. G. Block, "How Source of Arousal Affects Memory for Health Communications," Working Paper.

RESEARCH SUPPORT

Grant (sub-award): National Institutes of Health (NIH) (# TBD)
Admin Core for ROYBAL Center for Therapeutic Optimization using Behavioral Science
Major Goal: To develop messages to reduce COVID vaccine hesitancy.

Grant (sub-award): National Institutes of Health (NIH) (# 122876)
Admin Core for ROYBAL Center for Therapeutic Optimization using Behavioral Science
Major Goal: Leveraging Electronic Health Record Tools to Reduce Health Disparities for Patients with Hypertension.

Grant (sub-award): National Institutes of Health (NIH) (# 122146)
Admin Core for ROYBAL Center for Therapeutic Optimization using Behavioral Science
Major Goal: To develop principle-driven interventions to enhance the evidence-based use of prescription medications.

Grant (sub-award): National Institute on Aging (NIA) (#122150-MOD001)
Medication adherence
Major Goal: Optimizing electronic health record prompts with behavioral economic to improve prescribing for older adults.

Grant (sub-award): National Cancer Institute (# 5 PO1 CA72099-01)
Improving Cancer Risk Communication
Major Goal: To enhance informed decision-making and mammography for women by correcting misperceptions about breast cancer risk and the risks and benefits of mammography.

Grant (sub-award): National Cancer Institute (# 530464)
Increasing Sun Screen Adolescent Behavior
Major Goal: To educate adolescents about solar protection and influence sun protection behaviors among parents, coaches and adolescents.

Grant: National Endowment for Financial Education (# 20137)
Tailoring Retirement Savings Communication
Major Goal: To provide an implementation plan to enhance retirement savings among employees.

Grant: Social Security Administration (#19-F-10002-9-01)
Marketing Financial Literacy
Major Goal: To create and market audience-friendly financial literacy products.

INSTITUTION SERVICE

Tuck Executive Committee, 1998, 1999, 2000, 2002
Tuck Research Committee, 2000

Area Chair, 2002 to 2006
Tuck Admission Committee, 2004
Tuck Executive Education Committee, 1999, 2000, 2006
Dartmouth Capital Fund Raising Committee, 2000
Dartmouth Provost Search Committee, 2001, 2018
Dartmouth, Director of Business Development, ISTS, 2002-2003
Dartmouth, Vice President of Equity and Diversity Search Committee, 2007-2008
Dartmouth, General Council Search Committee, 2017
Associate Dean for Innovation and Growth, 2015 – 2018
Deputy Dean, 2018 – 2020
Senior Associate Dean for Innovation and Growth, 2020 - present

PROFESSIONAL ACTIVITIES

Area Editor, Journal of Consumer Psychology, 2015 - 2017.
Area Editor, Journal of Consumer Research, 1999 - 2003.
Review Board, Journal of Marketing Research, 1999 to present.
Review Board, Journal of Public Policy and Marketing, 2008 to present.
Review Board, Social Marketing Quarterly, 2014 to present.
Review Board, Journal of Marketing, 2015 to present.
Review Board, Journal of Marketing Behavior, 2015 to 2019.
Review Board, Journal of Consumer Research, 1994 - 2014.
Review Board, Journal of Consumer Psychology, 2002 - 2007.
Review Board, Marketing Letters, 1990 - 2003.
Ad Hoc Reviewer, Marketing Science.
Ad Hoc Reviewer, Journal of Experimental Psychology: Applied.
Ad Hoc Reviewer, Psychology and Health.
Ad Hoc Reviewer, American Psychologist.
Reviewer, American Marketing Association Conference, 1984 - 1992, 1997.
Reviewer, Association for Consumer Research Conference, 1983 - 2010.
Reviewer, AMA Doctoral Dissertation Competition, 1988, 1990, 1996, 1997.
Reviewer, MSI Doctoral Dissertation Competition, 1995 - 1998, 2001, 2003, 2005, 2007.
Reviewer ACR/Sheth Dissertation Award 2006 - 2008
Doctoral Consortium Faculty 1986, 1990, 1996, 2004, 2005, 2006, 2008, 2010, 2011, 2012, 2013, 2014, 2015, 2016, 2017, 2018, 2019.
Program Committee, Association for Consumer Research Conference, 1991, 1994, 1997, 2007.
Member ACR/TCR Advisory Committee, 2005 - 2010.
Co-Chairperson, Association for Consumer Research Conference, 2002.
C-Chairperson, Transformative Consumer Research Conference, 2007.
President-Elect, Association for Consumer Research, January 2007.
Member, Board of Academic Trustees, Marketing Science Institute, 2006 - 2010.
President, Association for Consumer Research, 2008.
Health Communication Advisor, Center for Disease Control, 2009 - 2014.
Co-Chairperson, Advertising and Consumer Psychology Conference, 2009.
Co-Chairperson, Advisory Board Member, CDC Annual Health Marketing Conference, 2010.
Fellow, Association for Consumer Research, 2018.

PRIOR DEPOSITION AND TESTIMONY OF PUNAM. A. KELLER

Deposition, State of Washington v. Johnson & Johnson, a New Jersey Corporation; Ethicon, Inc., a New Jersey Corporation, et al., Superior Court of the State of Washington, King County, Case No. 16-2-12186-1 SEA

Deposition and Hearing Testimony, State of California v. Johnson & Johnson, a New Jersey Corporation; Ethicon, Inc., a New Jersey Corporation, et al. Superior Court of the State of California and for the County of San Diego, Case No. 37-2016-00017229 CU-MC-CTL

Appendix B
Materials Considered

Court and Legal Documents

- *In Re: Valsartan, Losartan, and Irbesartan Products Liability Litigation,* No. 1:19-md-2875-RBK, Third Amended Consolidated Economic Loss Class Action Complaint, November 1, 2021.
- *In Re: Valsartan, Losartan, and Irbesartan Products Liability Litigation* , No. 1:19-md-2875-RBK, Expert Declaration of Rena Conti, Ph.D., November 10, 2021.
- *In Re: Valsartan, Losartan, and Irbesartan Products Liability Litigation* , No. 1:19-md-2875-RBK, Plaintiffs' Motion for Class Certification of Consumer, Third Party Payor, and Medical Monitoring Claims, November 10, 2021, Ex.
- Videotaped Deposition of Alphonse Borkowski, *In Re: Valsartan, Losartan, and Irbesartan Products Liability Litigation.*
- Videotaped Deposition of Antoinette Sims, *In Re: Valsartan, Losartan, and Irbesartan Products Liability Litigation.*
- Videotaped Deposition of Asha Lamy, *In Re: Valsartan, Losartan, and Irbesartan Products Liability Litigation.*
- Videotaped Deposition of Billy Bruner, *In Re: Valsartan, Losartan, and Irbesartan Products Liability Litigation.*
- Videotaped Deposition of Brian Wineinger, *In Re: Valsartan, Losartan, and Irbesartan Products Liability Litigation.*
- Videotaped Deposition of Brittney Means, *In Re: Valsartan, Losartan, and Irbesartan Products Liability Litigation.*
- Videotaped Deposition of Charles Johnston, *In Re: Valsartan, Losartan, and Irbesartan Products Liability Litigation.*
- Videotaped Deposition of Cheryl Mullins, *In Re: Valsartan, Losartan, and Irbesartan Products Liability Litigation.*
- Videotaped Deposition of Dennis Kaplan, *In Re: Valsartan, Losartan, and Irbesartan Products Liability Litigation.*
- Videotaped Deposition of Eric Erwin, *In Re: Valsartan, Losartan, and Irbesartan Products Liability Litigation.*
- Videotaped Deposition of Flora McGilvery, *In Re: Valsartan, Losartan, and Irbesartan Products Liability Litigation.*
- Videotaped Deposition of Gary Burnett, *In Re: Valsartan, Losartan, and Irbesartan Products Liability Litigation.*
- Videotaped Deposition of Gerald Nelson, *In Re: Valsartan, Losartan, and Irbesartan Products Liability Litigation.*
- Videotaped Deposition of Glenda Cooper, *In Re: Valsartan, Losartan, and Irbesartan Products Liability Litigation.*
- Videotaped Deposition of James Childs, *In Re: Valsartan, Losartan, and Irbesartan Products Liability Litigation.*
- Videotaped Deposition of James Lawson, *In Re: Valsartan, Losartan, and Irbesartan Products Liability Litigation.*
- Videotaped Deposition of Jay Meader, *In Re: Valsartan, Losartan, and Irbesartan Products Liability Litigation.*

- Videotaped Deposition of Jennifer Johnson, *In Re: Valsartan, Losartan, and Irbesartan Products Liability Litigation.*
- Videotaped Deposition of Joeseph Cacaccio, *In Re: Valsartan, Losartan, and Irbesartan Products Liability Litigation.*
- Videotaped Deposition of John Duffy, *In Re: Valsartan, Losartan, and Irbesartan Products Liability Litigation.*
- Videotaped Deposition of Joseph Kessinger, *In Re: Valsartan, Losartan, and Irbesartan Products Liability Litigation.*
- Videotaped Deposition of Jynona Lee, *In Re: Valsartan, Losartan, and Irbesartan Products Liability Litigation.*
- Videotaped Deposition of Lawrence Semmel, *In Re: Valsartan, Losartan, and Irbesartan Products Liability Litigation.*
- Videotaped Deposition of Leland Gildner, *In Re: Valsartan, Losartan, and Irbesartan Products Liability Litigation.*
- Videotaped Deposition of Linda Crocker, *In Re: Valsartan, Losartan, and Irbesartan Products Liability Litigation.*
- Videotaped Deposition of Lubertha Powell, *In Re: Valsartan, Losartan, and Irbesartan Products Liability Litigation.*
- Videotaped Deposition of Mark Hays, *In Re: Valsartan, Losartan, and Irbesartan Products Liability Litigation.*
- Videotaped Deposition of Marlin Anderson, *In Re: Valsartan, Losartan, and Irbesartan Products Liability Litigation.*
- Videotaped Deposition of Mary McLean, *In Re: Valsartan, Losartan, and Irbesartan Products Liability Litigation.*
- Videotaped Deposition of Marzanna Glab, *In Re: Valsartan, Losartan, and Irbesartan Products Liability Litigation.*
- Videotaped Deposition of Merlyin Andre, *In Re: Valsartan, Losartan, and Irbesartan Products Liability Litigation.*
- Videotaped Deposition of Miranda Dudley, *In Re: Valsartan, Losartan, and Irbesartan Products Liability Litigation.*
- Videotaped Deposition of Peter O'Brien, *In Re: Valsartan, Losartan, and Irbesartan Products Liability Litigation.*
- Videotaped Deposition of Radhakrishna Shetty, *In Re: Valsartan, Losartan, and Irbesartan Products Liability Litigation.*
- Videotaped Deposition of Robin Roberts, *In Re: Valsartan, Losartan, and Irbesartan Products Liability Litigation.*
- Videotaped Deposition of Ronald Molinaro, *In Re: Valsartan, Losartan, and Irbesartan Products Liability Litigation.*
- Videotaped Deposition of Samuel Cisneros, *In Re: Valsartan, Losartan, and Irbesartan Products Liability Litigation.*
- Videotaped Deposition of Sandra Kelly, *In Re: Valsartan, Losartan, and Irbesartan Products Liability Litigation.*
- Videotaped Deposition of Sandy Bell, *In Re: Valsartan, Losartan, and Irbesartan Products Liability Litigation.*

- Videotaped Deposition of Talsie Neal, *In Re: Valsartan, Losartan, and Irbesartan Products Liability Litigation.*
- Videotaped Deposition of Veronica Longwell, *In Re: Valsartan, Losartan, and Irbesartan Products Liability Litigation.*

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